UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

November 27, 2023
(Date of Report (date of earliest event reported)

IRIDEX CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**000-27598**	**77-0210467**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

1212 Terra Bella Avenue
Mountain View, California 94043
(Address of principal executive offices, including zip code)

(650) 940-4700
(Registrant's telephone number, including area code)
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.01 per share	IRIX	Nasdaq Global Market

Item 8.01. Other Events.

On November 27, 2023, IRIDEX Corporation issued a press release discussing its successful appeal for broader coverage of cyclophotocoagulation. The press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

This information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 27, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IRIDEX CORPORATION

By: /s/ David I. Bruce
David I. Bruce
President and Chief Executive Officer

Date: November 28, 2023

Iridex Corporation Announces Successful Appeal for Revision of Recent Medicare LCDs to Provide Broader Coverage of Cyclophotocoagulation

MOUNTAIN VIEW, Calif., November 27, 2023 -- Iridex Corporation (NASDAQ: IRIX), a worldwide leader providing innovative and versatile laser-based medical systems, delivery devices, and procedure probes for the treatment of glaucoma and retinal diseases, today announced its successful advocacy for revision of the recently issued Medicare Local Coverage Determinations (LCDs) for Cyclophotocoagulation (CPC).

During the last few days, the five Medicare Administrative Contractors (MACs) that issued the new LCDs have all corrected errors in criteria for coverage of CPC resulting in significantly broader patient qualification in the jurisdictions of these MACs.

“We appreciate the MACs quick action, before the Effective Date of the coverage change, to assure broader patient access to the benefits of CPC,” said David Bruce, Iridex President and CEO, “and that this correction was supported by strong advocacy from the original authors of the 2001 paper cited by the MACs in setting the new coverage criteria, led by Dr. Shan Lin from the Glaucoma Center of San Francisco.”

The change in criteria better aligns the LCDs with the conclusions and recommendations made by the authors of the 2001 paper, “Cyclophotocoagulation, A Report by the American Academy of Ophthalmology (AAO),” by mirroring several of the recommended indications. Specifically, the list of patient characteristics used in the criteria, which had been separated by the word “AND,” are corrected to be separated by the word “OR” and read as follows:

“4. Cyclophotocoagulation will be considered medically reasonable and necessary for patients with refractory glaucoma when:
a. Have failed trabeculectomy or tube shunt procedures, OR
b. Minimal useful vision and elevated intraocular pressure, OR
c. Have no visual potential and need pain relief.”

Mr. Bruce continued, “While we are pleased with this initial coverage-enhancing step, we are preparing a subsequent appeal to further broaden the patient criteria qualifying for reimbursement in these MAC jurisdictions. We will urge MAC administrators to include the additional recommendations from the 2001 AAO paper that remain excluded from the current modified LCD to cover (i) patients that are poor candidates for invasive surgical procedures and (ii) emergency situations. Our appeal will also seek proper consideration of the technological advances and the large body of peer-reviewed clinical studies supporting a broad range of patient types, disease severities, and safety evidence for CPC during the 22 years since the AAO paper and further broaden patient indications for coverage.”

About Iridex Corporation

Iridex Corporation is a worldwide leader in developing, manufacturing, and marketing innovative and versatile laser-based medical systems, delivery devices and consumable instrumentation for the ophthalmology market. The Company's proprietary MicroPulse® technology delivers a differentiated treatment that provides safe, effective, and proven treatment for targeted sight-threatening eye conditions. Iridex's current product line is used for the treatment of glaucoma and diabetic macular edema (DME) and other retinal diseases. Iridex products are sold in the United States through a direct sales force and internationally primarily through a network of independent distributors into more than 100 countries. For further information, visit the Iridex website at www.iridex.com.

Safe Harbor Statement

This announcement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Act of 1934, as amended, including those statements concerning clinical expectations and commercial trends, market adoption and expansion, demand for and utilization of the Company's products and results and expected sales volumes. These statements are not guarantees of future performance and actual results may differ materially from those described in these forward-looking statements as a result of a number of factors. Please see a detailed description of these and other risks contained in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 20, 2023. Forward-looking statements contained in this announcement are made as of this date and will not be updated.

Investor Relations Contact
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